MAY 2 5 2001

K010563

510(k) SUMMARY

SUBMITTED BY:

David M. Hooper, Ph.D.
Manager of Clinical and Regulatory Affairs
Spinal Concepts, Inc.
12012 Technology Blvd., Suite 100
Austin, TX 78727

512-918-2700

February 23, 2001

CLASSIFICATION, COMMON OR USUAL NAME, DEVICE NAME

Classification name: Pedicle Screw Spinal System
Common/usual name: Posterior Spine Implants
Product classification: Class II
Proprietary name: End-to-End and Side-by-Side Connectors

PREDICATE DEVICE

The predicate devices are the spinal rods that were approved as part of the BacFix® Ti Spinal Fixation System under 510(k)'s K973687 and K983260, and the Isola Dual Transverse Rod Connector and the Isola Tandem Rod Connector sold by DePuy Acromed (K001470).

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR §807.92.

INDICATIONS FOR USE

The End-to-End and Side-by-Side Connectors are intended to extend a pedicle screw construct during complex primary and/or secondary surgeries. The connectors are designed as an adjunct to the BacFix® Ti Spinal Fixation System and are intended to stabilize the spinal operative site during fusion procedures.

The indications for the BacFix® Ti Spinal Fixation System are as follows. The indications are unchanged by the addition of these connectors.

The SCI BacFix® Ti Spinal Fixation System consists of a combination of components which include rods, hooks, locking wedges, screws, transverse connectors, end-to-end connectors, side-by-side connectors, cable-screws, cables and spinous process grommets which are indicated to provide temporary stability of the thoracic, thoracolumbar, or lumbar spine (T1 to S1).

When intended for pedicle screw fixation, implants are intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar and sacral spine: Degenerative spondylolisthesis with objective evidence of neurologic impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor and failed previous fusion (pseudarthrosis). Levels of pedicle screw attachment for these indications range from T1 to the sacrum.

In addition, when intended for pedicle screw fixation, implants are intended for treatment of severe spondylolisthesis (grades 3 and 4) of the vertebra in skeletally mature patients receiving fusion by autogenous bone graft having implants attached to the lumbar and sacral spine with removal of implants after attainment of solid fusion. The levels of screw fixation for these indications range from L3 to the sacrum.

When intended for non-pedicle, posterior screw fixation of the non-cervical spine, the indications are: idiopathic scoliosis, neuromuscular scoliosis/kyphoscoliosis with associated paralysis or spasticity, scoliosis with deficient posterior elements such as that resulting from laminectomy or myelomeningocele, spinal fractures (acute reduction or late deformity), degenerative disc disease (back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies), neoplastic disease, spondylolisthesis, spinal stenosis and failed previous fusion.

The cable-screws, cables and spinous process grommets are indicated for defect of pars lateralis and spondylolisthesis. Cables and spinous processes grommets may be used for interspinous wiring if additional stability is needed.

DEVICE DESCRIPTION

The Spinal Concepts, Inc. End-to-End and Side-by-Side Connectors are designed for use with the BacFix® Ti Spinal Fixation System, which was originally granted marketing clearance via K973687 on March 18, 1998 and subsequently via K983260 on October 21, 1998. The End-to-End and Side-by-Side Connectors are manufactured from medical grade Ti-6Al-4V ELI titanium alloy per ASTM F-136 and is intended to allow surgeons to extend a pedicle screw construct during complex primary and/or secondary surgeries. Use of the End-to-End or Side-by-Side Connectors is at the discretion of the surgeon and is not required when using the BacFix® Ti Spinal Fixation System.

The connectors consist of a titanium block and four setscrews. The End-to-End connector is a narrow block with the setscrews arranged linearly along the long axis of the block. Rods are placed end-to-end in the block and the setscrews tightened for fixation. The Side-by-Side connectors are shaped like a square. Rods are placed through the block in a side-by-side manner and again, the setscrews are tightened for fixation. Setscrews are tightened with a calibrated diamond driver that delivers a consistent amount of torque.

Both the End-to-End and Side-by-Side Connectors are manufactured in two sizes to accommodate both 5.5 mm and 6.0 mm spinal rods.

COMPARISON TO THE PREDICATE DEVICE

The End-to-End and Side-by-Side Connectors are significantly equivalent to the previously cleared spinal rods that are approved as part of the BacFix® Spinal Fixation System. Application of these connectors does not adversely affect the mechanical properties of these rods. In terms of fit, form and function these connectors are substantially equivalent to the Dual Transverse and Tandem Rod Connectors that are included as part of the Isola Spinal Fixation System sold by DePuy Acromed.

DISCUSSION OF NONCLINICAL TESTS

Biomechanical tests of the interface between the connectors and the spinal rods were conducted. These data were compared to other connections in the pedicle screw construct. Testing was conducted according to ASTM standards. Corpectomy model testing using joined spinal rods was compared to tests using intact rods. Test data indicated that these connectors can successfully increase the length of a construct without compromising strength.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 2 5 2001

David M. Hooper, Ph.D.
Manager of Clinical and Regulatory Affairs
Spinal Concepts, Inc.
12012 Technology Boulevard, Suite 100
Austin, Texas 78727

Re: K010563
Trade Name: End-to-End and Side-by-Side Connectors
for use with the BacFix® Ti Spinal Fixation System
Regulation Number: 888.3070 and 888.3050
Regulatory Class: II
Product Code: MNI, MNH and KWP
Dated: February 23, 2001
Received: February 26, 2001

Dear Dr. Hooper:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative and
Neurological Devices
Office of Devices Evaluation
Center for Devices and
Radiological Devices

Enclosure

INIDICATIONS FOR USE STATEMENT

510(k) Number (if known): K010563

Device Name:

Spinal Concepts, Inc. **End-to-End and Side-by-Side Connectors**

Indications for Use:

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The indications for the BacFix® Ti Spinal Fixation System are as follows. The indications are unchanged by the addition of these connectors.

The SCI BacFix® Ti Spinal Fixation System consists of a combination of components which include rods, hooks, locking wedges, screws, transverse connectors, end-to-end connectors, side-by-side connectors, cable-screws, cables and spinous process grommets which are indicated to provide temporary stability of the thoracic, thoracolumbar, or lumbar spine (T1 to S1).

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use: X OR Over-The-Counter: _____
(Per 21 CFR 801.109) (Optional Format 1-2-96)

for Robert Chelland

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K010563

When intended for pedicle screw fixation, implants are intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar and sacral spine: Degenerative spondylolisthesis with objective evidence of neurologic impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor and failed previous fusion (pseudarthrosis). Levels of pedicle screw attachment for these indications range from T1 to the sacrum.

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When intended for non-pedicle, posterior screw fixation of the non-cervical spine, the indications are: idiopathic scoliosis, neuromuscular scoliosis/kyphoscoliosis with associated paralysis or spasticity, scoliosis with deficient posterior elements such as that resulting from laminectomy or myelomeningocele, spinal fractures (acute reduction or late deformity), degenerative disc disease (back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies), neoplastic disease, spondylolisthesis, spinal stenosis and failed previous fusion.

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The cable-screws, cables and spinous process grommets are indicated for defect of pars lateralis and spondylolisthesis. Cables and spinous processes grommets may be used for interspinous wiring if additional stability is needed.

After solid fusion occurs, these devices serve no functional purpose and should be removed. In most cases, removal is indicated because the implants are not intended to transfer or support forces developed during normal activities. Any decision to remove the device must be made by the physician and the patient, taking into consideration the patient's general medical condition and the potential risk to the patient of a second surgical procedure.

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